Vocabulary Task Force Public Hearing
Draft Transcript
September 2, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, everybody, and welcome to day two of the Vocabulary Task Force Hearing. This is a Federal Advisory Committee Hearing, which means there will be opportunity at the end of the meeting for the public to make comment. Just a reminder for committee and panelists to please identify yourselves when speaking for attribution because we do keep a transcript of all of our meetings.

Let me begin by having the Workgroup members, the Task Force members, introduce themselves, beginning on my right with Marjorie.

Marjorie Rallins – AMA – Director, CPT Clinical Informatics
I'm Marjorie Rallins from the AMA.

Stuart Nelson – NLM – Head, Medical Subject Headings Section
Stuart Nelson from the National Library of Medicine.

Betsy Humphreys – National Library of Medicine – Deputy Director
Betsy Humphreys, National Library of Medicine.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Jamie Ferguson, Kaiser Permanente.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Floyd Eisenberg, National Quality Forum.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Chris Chute, Mayo Clinic.

Patricia Greim – VA – Health System Specialist: Terminology
Patty Greim, VA.

John Klimek – NCPDP – VP Industry Information Technology
John Klimek, NCPDP.

Judy Sparrow – Office of the National Coordinator – Executive Director
I know we have a few Task Force members dialing in. Is anybody on the phone?

Eric Strom – DoD Military Health System – Program Management Support
This is Eric Strom for Nancy Orvis from DoD.

Judy Sparrow – Office of the National Coordinator – Executive Director
Anyone else? With that I'll turn it over to Jamie Ferguson.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much, Judy. I just want to again, as yesterday morning, set the stage for today by reflecting back. This task force held a hearing back in March. Many of these panelists were present there and we're trying to ask different questions this time. That hearing focused on the governance requirements, who needs to do what, how should decisions be made and so forth with regard to vocabularies for meaningful use.

One of the themes that we heard loud and clear throughout many of the presentations and discussions there, especially from the implementers, the purchases of electronic health record systems, the implementers and those who would be applying for the meaningful use incentives was they wanted to have one-stop shopping. The phrase kept coming back, "We want one place to go. We need centralization," and, "Make it easy for us to obtain the value sets that are needed, particularly for the measures related to meaningful use. But really, value sets related to the meaningful use program, as well as subsets for the convenience of implementers, whether they were subsets for a particular specialty or a particular disease subject area, as well as the entire taxonomies themselves. Make it easy for us to have one place to go to get things."

So today, like yesterday, we're focusing on this concept of one-stop shopping and what the infrastructure requirements might be. The overall questions that we've asked—and I think everyone has very nicely addressed the questions that we sent—the overall question is what does one-stop shopping look like? What does that mean to you? What's the ideal state? Then also, which of the requirements within that ideal state are the most critical, the most urgent? If we have to do things one step at a time what comes first? Also, what's most important and how should things be staged over time in order to achieve that end state?

Now, we did have three panels yesterday with a wide ranging discussion. I'll just recap a couple of the themes that we heard out of yesterday's discussion. One was the absolute criticality of versioning and managing distribution, as well as setting expiration dates on the distribution of value sets.

Then another theme was across stakeholder involvement in both the development and the review of value sets. Related to that is the need for clear attribution of ownership, so ownership. Some folks felt that that should always be attached to the original developer of a value set. Others too felt that across stakeholder, but regardless of what the structure of that ownership is, clear ownership was a clear theme.

Another thing that we discussed yesterday was the need for having a clear context for value sets, uniquely establishing the suitability for purpose. And also so that a context description then could be used to control what we refer to as off-label use of value sets and have a clear understanding of different purposes for different sets.

We had, I would say, another theme of a plea for simplicity and harmony with mechanisms for handling exceptions. So this was, I think, very notable in our discussion with the folks who deal with small physician offices, who just don't have staff to deal with these things and they just want both, licensing and other things, to just be managed for them. And if they have downloaded a subset that they're using that doesn't have something, they want an easy way to look up a term or concept that they need so that they don't just always revert to free text or some shorthand.

Then last, but certainly not least, we did have a recurring theme of intellectual property issues as a barrier to implementation. We had a few different approaches discussed there.

So that's just a brief recap of some of the major themes from yesterday. What I'd like to do for this morning is we have the biographies in the materials that everybody has. I'm not going to go through those, but I would like to ask all of the panelists, please, to introduce themselves. Then we'll start off with Ken and we'll go through the oral presentations and then we'll get into panel discussion.

If we could just start, Ken, from your end and just ask everybody to introduce themselves, who you are, where you're from and then we'll get into your brief presentations?

Ken Buetow – National Cancer Institute, National Institute of Health
I'm Ken Buetow. I'm from the National Cancer Institute and the National Institute of Health.

Brian Levy – Health Language – Chief Medical Officer
My name is Brian Levy. I'm the Chief Medical Officer at Health Language.

Russ Hamm – Apelon
Russell Hamm with Apelon.

Frank Naeymi-Rad – Intelligent Medical Objects
Frank Naeymi-Rad, IMO.

David Dobbs – SAIC
David Dobbs with Science Applications International Corporation.

Lee Min Lau – 3M
Lee Min Lau from 3M.

Harold Solbrig – Mayo Clinic
Harold Solbrig from the Mayo Clinic.

Suresh Srinivasan – National Library of Medicine
I'm Suresh Srinivasan from the National Library of Medicine.

Regis Charlot – Intelligent Medical Objects
Regis Charlot from IMO.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Now I think we're ready to have your brief presentations and then after that we'll have a wide ranging discussion.

Ken Buetow – National Cancer Institute, National Institute of Health
I want to thank you all for the opportunity to share the National Cancer Institute's perspective on the requirements and priorities for vocabulary infrastructure that would provide an ideal one-stop shop for meaningful use. For background: NCI uses both terminologies and value sets as part of our CaBIG program, a national network connecting the cancer community, to develop and describe information models, for data elements, for data types. They serve to define the metadata for public interfaces to information systems to enable semantic interoperability, both in research and care in our efforts.

Our efforts also provide a framework and foundational basis for other agencies and organizations, including the U.S. Food and Drug Administration, the Clinical Data Interchange Standards Consortium, the National Council of Prescription Drug Providers, to create, publish and maintain their terminology subsets and metadata in support of multiple purposes, including regulatory reporting, FDA submissions and pharmacy communications.

My written comments dealt with many of the detail questions that you raised. My verbal comments today will focus on general issues. First, with respect to essential elements, there are several requirements that we feel are important, many of them, actually, to be honest, quite obvious, but as with anything, being that I'm the first this morning I get to actually say the obvious things and then other people can censor their comments.

Critical requirements are high up time and full redundancy. As with any key production system, ideally, contents should flow to localized repositories in a way similar to domain name services that flow from a primary source of truth to local systems that maintain and synchronize copies for better performance. Rapid turnaround for new or modified concepts in vocabularies and additions and changes in value sets. We find from our experience sometimes that needs to be 24 hours or less, especially if this is the definitive source of information that folks are using.

We need the acceptance of multiple vocabularies for specific purposes rather than single vocabulary. Clear and easy mechanism for community input with regard to vocabulary content. Again, many of these

harmonizing with the themes of the last day's presentations. Multiple versions of standards maintained to support users, who update terminologies and value sets at different times.

We actually have points more general in nature that we think are critical related not just to the essential entities, but also to the general questions about how you go about rolling this out. We feel strongly that the centralized serving of terminology should be complemented by a federated mechanism for content generation to achieve the necessary agility and responsiveness in clinical context required for meaningful use.

Our experience suggests that domain federation, as a source of terminology, provides a scalable approach to staging over time. In other words, you don't have to boil the ocean. You don't have to do everything all at once. You can divide and conquer and flow up from individual subgroups. In this model, domains of interest define the content specific to their domain so that they can be integrated into larger compendium of cross-domain semantics via a centralized process, thereby, maximizing the relevance of domain specific terminologies in domain specific contexts.

We believe that a layered semantic space should be considered against having a flat file of terminologies or value sets. In this approach information, data type and terminology models are all supported and inter-linked with over arching ontologies. This layered approach of defining semantics would enable localization of terminology or metadata to be defined in relation to the standard in terms of constraint or extension and mitigates the potential conflict between the need for localization support versus the centralized data submission and integration.

We believe value set support under the HL-7, OMG compliance services could include services to create, manage, organize, search and retrieve value set specifications to record extensive metadata about them, including the reason the set was created, its intended purpose, reasonable responsible parties and their contact information, version, history, terminologies and terminology versions from which the set is drawn, so using a services framework in order to be able to project these specific specializations. Subsets and value sets, as well as then terminologies, terminology maps and extensions generally could then be built for specific operational uses, but still roll up into the master sets.

It's important that the information be provided about the purpose of subset or value set, its prominence, currency, intellectual property limits and other information pertaining to sustainability for use, ideally, as an organic part of the set or value set.

With that I'll turn the microphone over to others or however the format is.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think we're just going to start from one end and go down around the table. So, Brian, I believe you're next.

Brian Levy – Health Language – Chief Medical Officer
Once again, thank you for the opportunity to present once again to this group. I think it's a great idea that we're able to bring both, vendors and the academic world into this forum to be able to share some of our ideas and also share some of our real word, practical experiences as well.

Just to reiterate a couple of the major points that I made last time I was here: I certainly do agree that whenever possible having a central organization like the National Library of Medicine to be a repository for all of the terminologies, content sets, subsets, value sets that are applicable to meaningful use is certainly a useful paradigm. For purposes of this talk I sort of refer to all of these different terminology artifacts as what we call content sets, so these would include value sets, the subsets and all of the other sorts of bits and pieces of things.

Now, with that said, I think from a technology point of view having these content sets available in simple to extract, download formats is going to be extremely useful. I think having them in the UMLS format will be useful, but many folks may also want simply separate downloads of various subsets, various content

sets, separate from the UMLS just to make it easier. We're sort of increasingly, and somewhat surprisingly, seeing hospital sites themselves wanting to validate that their vendors are indeed using the right kinds of terminology sets and certainly, if you talk about those kinds of users, they're not going to necessarily have the right skill sets to be able to use the UMLS tools and so making it easier for them to see this is the appropriate subset, this is the appropriate piece of this particular terminology.

I think along with this, certainly, we need to have appropriate versioning so that it's very clear what the version of each of these content sets are, that it's very clear what the dependencies are so that a particular subset needs to be dependent on a certain lease of its underlying terminology and I think, as many of us have written in our testimonies, whenever possible to alleviate some of the licensing issues. It's certainly a challenge for the end user customers. It's a challenge for the terminology service vendors, like us, to try to ensure that our customers have the appropriate licensing.

With that said, I think it may also be useful to have simple terminology services available from a development point of view so that those more sophisticated users, who want to retrieve the terminologies from this site via a terminology service could take advantage of that.

Now, I would characterize that this is what we would call a development terminology server, which would be different from a run-time server, which is something that a physician would be interacting with at the point of care, which would require a much higher degree of performance and up time and all of that stuff.

With that said, despite all of this, I think we all recognize that this won't be a one-stop shop for all things related to terminologies. There are going to be lots of other different kinds of terminologies and content sets that are still going to continue to be available from other kinds of sources. We've got ICD-10-CM, which is obviously a large set of content. We see that there's going to be lots of different kinds of mappings and other issues related to that.

Not that I'm arguing that this service should include all things related to it; I think we just have to understand that this will be one area where we can get a large set of content from, but it certainly won't be the only area.

Of course, we will need to see vocalization. We're certainly seeing the end user sites wanting to be able to extend and modify the base terminologies. In fact, we at HLI have released a Web based, simple terminology subset and mapping tool called the LEAP application because we are actually increasingly seeing hospital sites themselves who want to be able to, for example, manage a patient, a physician friendly terminology to be able to localize it, to be able to create subsets of it. We aren't seeing that these users want to create their own sort of terminologies. What we are seeing is the increasing need to want to map their local lab codes to the LOINC standard or to create a smaller subset of the NLM core subset that's applicable to a hospitalist or other kinds of specialties or to be able to add additional kinds of synonyms that they feel might be missing. So with that said, we certainly see that there's going to be increasing need for these local terminology servers.

One other major point is we are also seeing that with the increasing adoption and acceptance of using the Web services that there may not be the need so much to have these heavily deployed local terminology services and some of these types of applications can be run off of a Web services or in the so-called cloud.

With that said, once again, I thank you for the opportunity.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Next up is Russ.

Russ Hamm – Apelon
Thank you and good morning. Russ Hamm representing Apelon. Apelon would like to thank the Committee for this opportunity to provide input on the deliberation of the requirements for vocabulary infrastructure to provide a one-stop shop for delivering subsets, value sets and terminologies.

I've been involved in informatics, specifically in terminology infrastructure development, for approximately eight years and served two terms as HL-7 Vocabulary Workgroup Co-Chair. As an informatics architect of Apelon I've been involved in developing terminology service infrastructure with the goal of improving the access, maintenance, dissemination of structured terminology content. We're in agreement with the focus of this committee that semantic interoperability is a crucial element of the value set or value proposition for deploying healthcare information technology and that semantic interoperability using structured terminology can only be assured if the mechanisms used to access and share content are equally consistent, a fundamental requirement of a one-stop shop to deliver terminology artifacts or terminology services.

Terminology services are the components that enable the consistent, programmatic access of terminology content in a way that centralizes terminologies and represents them in a consistent way, provides for the dissemination of terminology content predictably, integrates with other terminology enabled applications and delivers terminology artifacts in accordance with a single consensus standard content model and corresponding data format.

The current reality is that today's available terminology services vary widely in scope and capability. This variance in scope reflects the differences between the local requirements of the users of those services, so what's required is a robust, common terminology service, a common terminology service developed as part of a consensus based process to standardize parameters for public and private sector tooling to make vocabulary searchable and discoverable will enable a one-stop shop through the provision of controlled and consistent access to vocabulary artifacts for meaningful use.

By identifying the points of commonality for terminology services consistent and expected behaviors of a common terminology service can be defined. These agreed upon behaviors and interfaces represent the necessary conformance points for terminology service center operability. In support of the requirement of a consensus based, one-stop shop, Apelon and Mayo have invested in and provided leadership in the joint HL-7/OMG effort to develop Common Terminology Services Release 2.

As a project of the HL-7 Vocabulary Workgroup CTS2 has the goal of providing standard consensus based interfaces to enable the dissemination and management of structured terminologies. CTS2 is an extension of the existing HL-7 CTS specification, which is both, an NCN ISO standard, specifies query interfaces for terminologies. CTS2 moves the standardization of terminology service interfaces from the existing read only capabilities specified in the initial CTS1 specification into the domains of terminology administration and terminology content offering, including subsets, value sets and mappings.

As a functional model, CTS2 provides several important benefits. Terminology and terminology software developers benefit from having the functional requirements of the service clearly specified as part of a consensus standard. The value of this consensus standard is evidenced by organizations, both federal, national and international, who are already building CTS2 capabilities into their existing terminology service infrastructures well ahead of the official standard technical specification being released. CTS2 is anticipated to be voted on and be available as a specification and reference implementation in March of 2011 and will support meaningful use by providing a common infrastructure component that enables either centralized or federated repositories to be accessed consistently by a large community of terminology users.

Once again, we'd like to thank the Committee for this opportunity and turn the mike over.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Frank is up next.

Frank Naeymi-Rad – Intelligent Medical Objects – CEO
Thank you for this opportunity to participate in this hearing. I'm Frank Naeymi-Rad, CEO of Intelligent Medical Objects. Also with me is Mr. Regis Charlot, our CTO, who has worked very active in our distribution models. We are vendors, so we can participate in answering questions.

IMO develops, manages and licenses medical vocabularies to vendor partners for use in electronic health records. Our systems are ... suite of … products, include IMO Problem IT and IMO Procedure IT, which provide seamless mapping of diagnoses and orders terminologies to regulatory billing codes and mandated medical concepts, enhancing ... support research, patient education and financial operations. IMO provides tools necessary for healthcare organizations to support uniform labeling of healthcare profiles, services rendered and outcomes across their enterprise. This intersection of clinical and financial data provides healthcare organizations with dependable, quality information to deliver service, bear risk and to enable efficient, cost effective operations and accountability.

IMO terminology products improves physician satisfaction, facilitates physician adoptions of our vendor partner EHR and point of care applications. They speed the coding process, reduce unnecessary distractions associated with the physician/coder communications and result in fewer rejected claims. Our experienced team of medical informaticists, terminologists, clinicians, health informations management professional and software engineers provide our vendor partners a just-in-time vocabulary outsourcing partner for their EHR solution.

IMO's mission is to provide innovative, medical informatics products that empower the clinicians, improve decision making and efficiency in order to realize better healthcare. I guess let me re-emphasize better healthcare. Therefore, we appreciate the opportunity to provide input to the Task Force on the benefit of value sets and subsets. We understand the importance of and appreciate the honor of working with the Task Force in this regard. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think next up is David.

David Dobbs – SAIC
Good morning, members of the HIT Standards Committee and Vocabulary Task Force. I am David Dobbs and I serve as the Director of Medical Informatics for the Health Solutions Business Unit of Science Applications International Corporation. Speaking on behalf of our Medical Informatics Team I want to thank you for giving me the opportunity to provide our thoughts on what constitutes the right set of requirements for a one-stop shop for vocabulary infrastructure and which of those requirements should have the highest priority given the drive to achieve the goals of EHR meaningful use.

SAIC has been engaged in informatics and information technology development in the healthcare, public health, life sciences domains for many years. We've been active participants in the development of standards within HL-7, CDISC and HITSP. SAIC assisted the CDC on the public health information network by developing and maintaining implementation specifications and their associated value sets. We were the original developers of the CDC's ... that makes value sets of interest to public health available through a Web site.

SAIC's vision for a one-stop shop for vocabularies and value sets is in large part embodied by an internally developed enterprise vocabulary management and distribution system called the Terminology Management and Provisioning Service or TMaPS. TMaPS is an Open Source software application that consists of a centrally maintained vocabulary server that stores vocabularies, value sets and maps. Vocabulary consumers are given a vocabulary server, a local vocabulary server, through which they can subscribe to and receive vocabulary updates from the central vocabulary server. The local vocabulary server can be integrated into local EHR software, interface engines and other health applications. Choosing the right vocabulary content to place into a one-stop shop is important.

HHS, ONC's meaningful use rule, identifies multiple types of vocabulary content that should be distributed through the one-stop shop. It identifies a set of vocabulary standards for problems, procedures, laboratory test codes, medications, vaccines. It also identifies ten implementation specifications that reference literally hundreds of different value sets and those value sets are maintained by a host of different, separate organizations, including HL-7, ASTM, NCPDP and HITSP.

Also within the one-stop shop there are value sets associated with calculating the numerator, denominator and exclusion criteria for the clinical quality measures. In total, there are hundreds of value sets that are required to meet all of the EHR meaningful use requirements.

In addition to vocabularies and value sets, implementers will need concept mappings between standard concept codes in order to meet some of the EHR meaningful use requirements. An example of a need for maps is highlighted by the HHS/ONC selected HITSP C32 Patient Summary document. Generating the C32 document is one way to meet the core meaningful use objective for providing patient clinical summaries.

The conformance rules that HITSP developed for the C32 document require that problems and procedures be encoded using only SNOMED CT codes. In order to conform to the HITSP C32 Patient Summary Implementation Guide and to pass the NIST C32 conformance testing requirements implementers will need to have mappings between ICD-9, CPT and SNOMED CT. Likewise, ICD-9 to ICD-10 mappings will be needed for stage two meaningful use.

Now I'd like to turn my attention to the functionalities needed by a one-stop shop. Developing a centralized vocabulary distribution source requires a well crafted canonical data model for storing direct ... vocabulary objects. When SAIC developed its own vocabulary distribution software, TMaPS, we spent a considerable amount of time designing a data model that took into account a number of important considerations. These considerations include following HL-7 vocabulary principles, such as storing vocabulary object identifiers and carrying a concepts coding system identifier into value sets and maps.

We looked at the ISO 1179 standard to help identify appropriate metadata for vocabulary objects, such as the source name, release date, definition and licensing information. We made sure we could clearly identify the authority that is responsible for developing and maintaining the vocabulary object and we ensured that all vocabulary objects were appropriately versioned. The canonical data model for the one-stop shop needs to be kept as simple as possible so that it's easily understood by those implementing vocabulary within their EHR and health applications; however, the canonical data model needs to have the proper links to tie back to the more powerful and complex concept models, such as those from the UMLS Metathesaurus, RxNORM and NCI Thesaurus. Other important considerations for a one-stop shop include creating groupings of vocabulary objects that support specific use scenarios, such as the group of value sets and maps required to implement a specific implementation specification or a quality measure.

Vocabulary users need the ability to subscribe to vocabulary sets and individual vocabulary objects. When changes occur to those vocabulary objects subscribers should automatically receive a notice of the change and optionally have those changes sent to them. A Web based user interface is needed for viewing, browsing, searching and downloading the vocabulary objects. The downloaded vocabulary objects needs to support multiple formats, including XML, Character Delimited and Excel.

Finally, a vocabulary distribution source should include information on vocabulary principles and best practices to educate those who are trying to implement vocabulary into their EHR systems and health applications. Lay vocabulary users need practical knowledge, such as the different uses of object identifiers for coding systems and value sets, why vocabulary version is important and how to look up the meaning of a concept code. Making vocabulary objects available through a distribution source will do no good if those who have to implement vocabulary objects do not understand the basic vocabulary principles.

Again, I thank you for giving me the opportunity to share our experiences, lessons learned and opinions of what constitutes the right set of requirements for a centrally managed, one-stop shop for meaningful use vocabulary.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Lee Min, I think you're next.

Lee Min Lau – 3M

Hello, everyone. This is Lee Min Lau from 3M. I manage the 3M Healthcare Data Dictionary as 3M Terminology Services, so I guess you can consider us a terminology service vendor. So I'm sure you've heard a lot of very good comments as ... I'm sorry I couldn't make it yesterday. It sounds like I missed a very interesting discussion. So I'm just going to comment based on my experience over the past 15 years and it's probably still going to be obvious though, obvious comments, so I apologize in advance.

Now, I was very happy when I saw the term one-stop shop, because people have accused me of liking to shop, although the results are not really obvious. The point though is that when you say one-stop shop even you should just say the word shopping it means different things to different people, you know. I can tell you if you ask Nordstrom's they'll say, "Yes, we are a one-stop shop." If you ask Costco they'll say, "We are a one-stop shop," but definitely they provide very different products and different shopping experiences and you go to them for different reasons.

So, when you say one-stop shop here for value set and subset what is it you're trying to achieve and what is your target, right? So, for instance, the obvious ones that I've seen from the written testimonies are that you want to provide subsets and value sets ... and then you want to help manage licenses. You want to help manage updates.

Now you also want to help them implement. Is this a one-stop shop one way or two way, meaning is it just the distribution or do you also want to get user feedback? What about managing or helping the local customizations? Do you want to then establish mechanisms for synchronizing everything? I mean you can really go from very simple to very complex and maybe you want to do it all in stages.

There's nothing wrong with that. The thing though is to gather the kinds of requirements not only from a technical and functional point of view, but also from, I want to call it, experience of process or purpose point of view. So, for instance, you might say on extreme end you may have an organization that can already do a lot of it from a technical point of view, so let's say the heavy stuff, the technical people and what they need help for is the actual value set and subset, so your first stage would be for you guys; all you want is a place to download your value sets and subsets. Fine. This is what you do.

Other organizations would be the opposite; strong in content because they have been focusing on what they want to do with the data, but they don't want to handle the technical details and all of that. You may have to then also accommodate those ....

What I'm trying to say is that you want to have the steps of this one-stop shop, maybe step is the wrong word, but steps of the processes, steps of the goals, whatever you want to call it. Lay it out and be very clear as to what you are trying to do. Most of the time people seem to be okay as long as they understand your expectations. They may grumble, but if you say this is all we're trying to do here now they can accept it. So the first step could be that all we are going to try to do is provide you a place where you have a listing of all of the value sets and subsets and for each value set or subset we state clearly what it is for, what it is not for, maybe provide examples of how it can be used and then overall, for your one-stop shop, you could lay out future plans. I mean I think things like that would go a long way to help people ease up on a sense of this overwhelming, huge job in front of them.

The last thing I will actually say is you probably cannot please everyone and you probably cannot even please anyone no matter what you do. You know you're going to get complaints, so you might as well just state what you believe will do the most good, whether the rest of us believe or agree with it or not, because we probably won't anyway. Just provide the information that you think will help. If you have the case laid out that this is what each thing you provide is supposed to do we can grumble all we want. It's clearly stated and the result will speak for itself.

So a few other things that I would comment about since I heard that there was a lot of discussion yesterday is IP and mapping. The IP part; I don't know, maybe I'm over simplifying; I don't know that people will really complain so much as long as, again, it's clear. For instance, take LOINC, take UMLS. Everything tells us we need a license. We still have to apply for it. We still have to provide yearly update

to UMLS to state what we're using it for. I mean those are just necessary evils that we deal with. So it's up to ONC or HITSP to decide how much or how little they want to do. Again, it's all a matter of expectation. UMLS has stated very clearly, "We do up to this. The rest of the users, you go get your own licenses."

Now, the mapping part then, again, also depends on the purpose. We talk about whether we want to map locally. We need to. I know there are extremes from totally ... to totally map everything. Again, it depends on what you can or cannot do, the constraints. If you have a site or a system that tells you straight out my system is fixed, I can't even add an additional column, I can't switch anything out of it. I have to continue using my code and I want to exchange vendor codes. There is your answer. You have no choice unless you then say, "All right. Then your alternative is throw out your system. Implement one that already has vendor codes."

All of these, I think I'm circling back to the same theme, which is that I would urge that you go through and identify your use cases, your audiences. Actually lay out the steps. Work from beginning to end; what it is you're trying to do. How do you do it? What is the end result you're trying to see? Based on that, just decide for yourself what it is you want to provide, how you're going to provide it. State the expectations clearly and then step back and just get ready for all of us to start yelling. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Harold is next.

Harold Solbrig – Mayo Clinic
Hello. I'm Harold Solbrig from the Mayo Clinic. I'm finding myself in the position of simply repeating a lot of what's come in front of me, but perhaps I can take a little different perspective. I think one of the first things that we want to be aware of is that value sets seem simple, but they're just the surface of terminology, structured terminologies, ontologies and the resources behind them.

If we're talking about meaningful use we're implying shared meaning. That means we can't lose track of the terminologies. If we're going to expose the value set we have to expose the structures and meaning and all of the work that goes behind it. A SNOMED code in isolation has no value. An ICD-9 code or an ICD-10 code without the use and the excludes ... has no value. That means we have to actually provide access to the meaning, as well as the code value sets, which in turn means that the one-stop shop and the distribution is not a simple process.

I have to agree with David. A consistent and well understood structure allows us to convey the meaning. Another point is we need the rights. It doesn't do us much good to have the rights to five SNOMED codes if we can't traverse the graph and understand what the intent of the SNOMED was. As we introduce this we are introducing complexity and we need software to access and manage that complexity.

Now, yesterday there was a call for simplicity and simplicity is often the most difficult task to accomplish. It's not a simple problem. If it was we wouldn't be here. We'd be done and we'd be going on. So use must be simple.

We need to put it out there in such a way that people can get at what's there and use it without specialized software, basically they need to be able to get at it with a Web browser. I point you at some excellent resources as examples, ... being one of them. The NCBO BioPortal, which is very interesting because they're discovering that it's being used—they or we; we're part of it—are being discovered that it's being used in places they didn't even know because it is easy to use.

Another example on a whole different line is the Eclipse SWT Toolkit for developers, which is a very complex process, but it comes with examples, just all sorts of things. If you need to do this, here is a code snippet to go about it.

So I think another thing we need to do is deploy software. Widgets that we can plug into Web applications that use the resources directly; .NET plug-ins for people that are familiar with Word and Excel

and more complex applications; JAVA fragments, etc., a set of tools that allows you to use it. One of the things I think we need to recognize on making it simple is that every bit of work that we do once up front is a piece of work that the consumers don't repeat 10, 100, 1,000-fold for everybody that has to implement it. More importantly too, every bit of work that we can do up front is a point where we have a common meaning rather than room for interpretation on how something is used.

I also want to mention that the access to the updates must be simple. This can't be a centralized resource. People have to be able to easily pull it behind firewalls. They have their own performance requirements. They have their security requirements. We don't want Google tracking access to terms from the Mayo Clinic basically. Being able to do that, we need to be able to do that easily to subscribe as suggested, either push, I just want updates when they occur; or pull, I want to know when updates occurred.

Furthermore, we need to know what the impact updates are going to be. We need to have updates arrive. We need to see what their effect is. It leads to actually the next topic, which is mapping. Lee Min addressed that. If we're going to be using this in existing systems we need to be able to map to what we pull down and if we take updates we need to know what the updates are about.

So we need tools that allow us to use this in our environment and they have to be useful. They have to be reliable. They have to give us access to all of the meaning that's in there. They have to be available at a low cost to the consumer. They can't have a high price of entry, which I wanted to note isn't the same as inexpensive. Everything I'm describing here is expensive. It's just who bears the cost of it.

Kind of another question that I heard rise and I think that's very important to understand: Meaningful use, understanding who is getting the meaningful use out of it, who is this targeted for and what gains they can expect to find out of it. It can't just be meaningful use to government tracking. It has to be meaningful use in terms of workflow and in terms of each of the consumer's ability to understand and better utilize their own information.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Suresh.

Suresh Srinivasan – National Library of Medicine
Good morning. As I said, my name is Suresh Srinivasan and I work at the National Library of Medicine. I am the Chief of the Medical Language Branch in the Office of Communications Systems Division of the library.

My staff and I work in concert with other groups within the library to develop tools and processes needed to produce some of the vocabulary products at the NLM, such as the Knowledge Sources of the UMLS or Unified Medical Language System, RxNORM and the Medical Subject Headings or MSH. We're also now starting to familiarize ourselves with the IHDS ... Workbench for use in maintaining a U.S. extension of SNOMED.

NLM has a long history and an ongoing mission of producing and distributing entire vocabularies, such as MSH, the NCBI Taxonomy, RxNORM, etc., as well as value added subsets, such as the core problem list subset of SNOMED CT and RxTerms. In addition, NLM is a producer and distributor of UMLS and RxNORM, which are concept based terminologies in a single unified format that links synonymous names and identifiers from disparate constituent vocabularies. NLM also develops tools to create, maintain, produce and distribute these vocabularies and related products to install, create custom subsets of the UMLS Metathesaurus, to facilitate Web based searching and browsing of these terminologies and to access the UMLS using Web services and to create various ... and NLP tools to improve search and retrieval. In our IHDS ... role as a U.S. national release center, NLM distributes the English and the Spanish versions of SNOMED CT.

NLM currently provides direct access to all of the major vocabularies and code sets required for meaningful use, either in the value added UMLS rich release format, also called RRF or in the native

format, hosted either at NLM or linked to other official sites. NLM has built an infrastructure for authenticated access to these and other resources around the UMLS licensing model. Users can sign up for a free license and then avail themselves of these resources via a portal Web site that has a single point of entry into the space.

The Web services API provides a secure method for third parties to authenticate a user as a UMLS licensee and an account holder. While this has been available for some time it has not been as well documented and publicized as we would like, so going forward we'll ensure that this is done in a better way. Such a remote authentication facility is important for developers and consumers of meaningful use vocabularies and related value sets, particularly if it uses data that requires a UMLS license.

A single license can have multiple user accounts associated with it for maximum flexibility. So, for example, a faculty member can sign up for a license and then permit her students to create accounts linked to that license. Licenses, as Lee Min mentioned, must be renewed annually and licensees must provide feedback in an annual questionnaire to help NLM improve our products.

On the terminology services front we are in the process of refining the Web services API to better align with the underlying UMLS domain model. Given that this is an active area of development elsewhere, such as at Mayo and Apelon. We will investigate layering other standard terminology services or service APIs like CTS2 atop that once we have it.

I agree with everything that's gone on before here with regards to versioning. A lot has been said. We also agree that it's important to have versioning for all of the artifacts, including value sets and that the repository that will be the one-stop shop for this information, wherever it may reside, has to be clear and unambiguous on the version information. It would also be important to provide access to the previous versions of the data with you. NLM produced vocabularies and subsets have explicit version information encoded in the name of the downloadable artifact and in some cases there is metadata in the terminology itself.

The UMLS Terminology Services does provide access to the archive of previous releases of the UMLS for traceability, comparability and for queries that span time. Similarly, all RxNORM and MSH data for prior releases are also available for download.

If you're creating value sets or maintaining them you will need ways to search existing vocabularies or code systems in very flexible ways to look for the content that you need. The UMLS has nearly ten million names for two million concepts, so one can cast a wide map to look for that meaning that you need. This becomes even more powerful when used in conjunction with NLM's ... tools. But in the event that the meaning does not exist elsewhere there needs to be a pathway for a way for the user to submit the request so that content can be added to standard vocabularies. We're currently working on ways to provide that, to do this in the context of the U.S. extension of SNOMED.

When a concept is accepted for addition an identifier in the U.S. name space will be available fairly quickly for use. Of course, as a fallback, one must have the option of creating extensions of value sets with local content, but then the update burden falls on the local organization.

The infrastructure to support these and many other important NLM applications is built on industry standards with security, reliability and scalability in mind. From redundant power supply, air conditioning, very mundane things, but it starts there in data centers to network attached storage, CPU virtualization. We also have redundant hosting sites for load balancing, disaster recovery or both. Of course, this also allows for software to be patched because we do have important security constraints without it breaking the service. We're also investigating infrastructure as a service and a cloud when that becomes reasonable.

Finally, NLM has built up resources in the area of customer support using toll-free telephone numbers, e-mail and list serves and has the ability to answer basic questions quickly, to route more advanced queries to experts and to point customers to a variety of educational resources.

Another focus for NLM is documentation and training, something we can all agree is key for better understanding and ease of use. Thank you very much.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I want to thank all of our panelists for their verbal presentations here today. Now we have a good chunk of time this morning for a wide ranging discussion. I see some cards already going up here. I'm going to take my prerogative to ask the first question of the panel and this has to do with what might be considered an irreducible minimum starting point of services.

What I'm going to say, as in previous discussions and much of the discussion so far here this morning, I think we've heard that if we're going to do anything we have to have an ability to download specified value sets, for example, for quality measures and potentially other sets that may be required as part of meaningful use incentives program or certification program. I think we've also heard then a strong desire to have, at a minimum, a simple query capability, which might be the original CTS or it might be something more, but some sort of a simple query capability as an absolute minimum. I think that—and I'm talking about now for end users of the EHR—the first question that I want to ask is what else do you consider a minimum, a minimum starting point? I heard some various opinions expressed just here, but that's my first question is what's the minimum. Brian, please.

Brian Levy – Health Language – Chief Medical Officer
Yes. I think one other thing that would be fairly useful is I think many of us have tried to sift through the several hundred pages of the meaningful use guidelines and actually, making it clear which sort of terminologies, which value sets apply to which specific parts of the meaningful use measures, making it clear not only for us, but as I said, I think that would be useful for the hospital sites to be clear on that. You know we've been asked, and as I said, somewhat in a surprising fashion by several CMIOs and other sorts of medical directors at individual hospital sites, "Well, are you sure that that is the right subset that we need to use for this case?"

We say, "Well, here, let's go to page 657 and we can sort of show you there." It would be much easier to say, "Look, here is one specific area where you can go to to be assured that you're using the right sets of content." I think that this is particularly important for these end users because they want to be assured that they're going to receive their ... stimulus money.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Other responses to that? Harold?

Harold Solbrig – Mayo Clinic
Well, to reiterate one part of the discussion is I think as soon as possible the selection of at least a core model and distribution structure that allows people to be assured that whatever they develop against will remain and will remain in a relatively stable fashion. I think once we agree on the structure we can very soon make stuff accessible again, ideally, just through HTTP, a URL that gives you a set of XML. That opens it up for a wealth of developers and users.

Now, the next step is once you've opened it up you want to make sure that things are used consistently and within the intended meaning, but certainly, being able to bounce how things end up being used off of the intent will give you the opportunity to then absorb the best of the development to correct where you think things are going astray and to gradually gather a collection of software resources that accompany this core structure.

Betsy Humphreys – National Library of Medicine – Deputy Director
Harold, can I just follow up on that? You have said the first thing to do is to come up with this core model and what have you and that makes a great deal of sense to me. So, given the players that you know well in the future is this an hour meeting or is this a grand debate?

Harold Solbrig – Mayo Clinic

Obviously, it lies somewhere within those two boundaries. No, I don't think it's a great debate. I think the community has reached the point where between the guidance given by the NLM and the vendor communities and the standards communities we have a pretty solid idea of what needs to lie at the core of this whole thing. Incidentally, the W3C community has been putting some of that in as well.

Certainly, the biggest debate is going to be on what we call the dang thing, so—

Betsy Humphreys – National Library of Medicine – Deputy Director
Oh well, always naming is always a problem. I guess I'm just making a point that I think we might want to use a less technically wonderful approach to answering Brian's thing, which is that he can point to something, which is an official place that says this is it so people are not second guessing whether his service has the latest one or the right one or whatever. We may want to attack both problems at once because this sounds like a very immediate need if people need validation that whoever they're working with, whether it's the terminology service provider or directly with their EHR vendor or whatever that, in fact, these people know what they're talking about and they need to have an independent place to go to say yes, I see that they're using all of the right things.

Brian Levy – Health Language – Chief Medical Officer
I totally agree that we need a technical sort of format for this and certainly, as we've been saying, things like value sets are a lot more complex than just a simple list, but we do need to, as best as we can, boil it down to a simple list with the value sets and the subsets that these particular end user sites want to be able to look at. Obviously, even though I'm in entire agreement with all of these comments, the rest of this, the context is needed for the unsophisticated user who wants to be sure they're going to achieve meaningful use. The fact that your program is delivering the same set that the government says is the one they have to use to achieve meaningful use will be reassuring and help move this along I would assume.

Frank Naeymi-Rad – Intelligent Medical Objects – CEO
I guess there is another minimum part that of the implementation, so let's suppose we do have a set. Now, how can this vendor implement it? I think, clearly, having a vocabulary service set that is maintained and managed and distributed, like having a U.S. extension to SNOMED, I think is a common denominator. You really need to get something that at least allows the vendor to utilize these architectures internally within their application and rely on it, because otherwise it's really a retrospective model ... model.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
David.

David Dobbs – SAIC
I wanted to comment a little bit on the question about, in meaningful use, what standards are identified and I think that's a very, very important question because the first thing you have to say is what do we need to control, what needs to be distributed. If you look at kind of something that I learned in going through and reading the CMS rule and the HSS/ONC rule around meaningful use is that the standards actually are in the very last part of the document, the last about three pages. So I got the pleasure of skimming through about 150 pages of comments and reconciliations of comments until I got to the meat and so that's kind of a tip for people looking for those standards.

It's a pretty easy thing to, once you find those standards, identify them; create a little cheat sheet for them; write a little Cliff Notes I would say. You were saying the piece about the model, how long would it take to create the model and just a little bit to add to what Harold said. I think the core pieces of the model people know very well. I think where the debate is going to be is what are the boundaries of that model. How complex does it get? Does it do everything that the UMLS Metathesaurus does or does it do just a very limited set of functionality around storing vocabularies, simple concept mappings, value sets, maps and that's it? I think that simple model I just described is what's really needed. I think the debate will be that's needed, but we also want to design this much more rich set of functionality into it.

Betsy Humphreys – National Library of Medicine – Deputy Director
Just to allay any fears, I don't think there's anyone in the world who thinks that the sort of basic, simple distribution model we're talking about here is ... format. I mean just to be sure. I don't think that one has any advocates.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Also, just to clarify, the way I was asking the question, I think what we've heard from users is their assumption is that a simple download is just an enumerated list of codes period. I think, Harold, you want to add on to that.

Harold Solbrig – Mayo Clinic
That concerns me deeply, because I think we can measure to an extent what we have to publish and again, meaningful use means shared meaning. If we publish a simple list of codes we ought to be able to measure whether they're used consistently and reproducibly and if they're not. I mean just take ICD-10 and throw away all of the includes and excludes; publish a set of codes and use those meaningfully. No. It isn't going to happen. You need that additional information. What we need to do is determine the minimal set of information we distribute to get the level of shared meaning that we require.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
That's exactly why I'm asking the question this way. I'm sorry.

Suresh Srinivasan – National Library of Medicine
On the question of a reducible minimum, I think in all of the discussion we have not really nailed down what the exchange format is for the value set specifications, because in the more complicated intentional value sets this can be a very involved expression expressed in XML or any other language. If that is the downloaded artifact there has to be a way for someone to expand it to the list of codes that meets that spec at any given moment. So I think we need both; we need the simple Excel downloadable list of codes, but also the spec that goes to create that list. Somehow the versioning has to be clear as to when this was generated, from what version of the spec for that value set.

In off-line discussions we've had, I think, CTS2 is working up a spec for the XML, but I think we can all collaborate on that and that would be a very good step.

Betsy Humphreys – National Library of Medicine – Deputy Director
To follow up on Harold's program thing, the other issue is who does what, because clearly, if you're dealing with a value set, however expressed, in many cases—certainly the kind we're talking about in this hearing—it goes back to be a subset, in essence, a very defined subset of a larger thing. The issue is you're trying to convey the meaning for this particular thing this is what's required.

And as we point out, I think the issue is, in some ways, at the product development side that you can implement the use of the terminology in an actual interface or whatever in an extremely brain dead way or you can, in fact, take advantage of this. If you don't take advantage of this you're not going to assist anyone who's using your product to do any kind of consistent data creation, but that is a very important aspect and we love to see tremendous competition and great advances with terminology services in EHR developers in all of this, but a central service, it seems to me, doesn't want to deliver something where you can't—you know I mean there is a certain piece of this, but the central service for distribution is not actually the place where you're actually building it into the product in a way that will assist.

Ken Buetow – National Cancer Institute, National Institute of Health
Except I think the central service has to expose that information—

Betsy Humphreys – National Library of Medicine – Deputy Director
Yes.

Ken Buetow – National Cancer Institute, National Institute of Health

So I think that's the point that several of us are trying to make is that the central service can't just simply be the flat representation, because these other competitions that we're talking about are going to need access to the context and access to the richer definitions and meanings. So clearly, there may be the need to have these simple presentations for limited use, but for the more sophisticated use that you're implying and I think that we're hoping will emerge in the more sophisticated systems you need to have access to that deeper representation.

Betsy Humphreys – National Library of Medicine – Deputy Director
Yes. I'm not disagreeing with that at all and I think that in some sense the simpler representations gets at some of these other issues, like how does somebody, who doesn't understand this, get a feeling that you know what you're talking about in your product or something.

M
Stuart, I want to inject something here. We can't have a common data model that requires that people understand meanings all of the time. I think if we do that achieving a common data model is going to be a ....

Stuart Nelson – NLM – Head, Medical Subject Headings Section
I'd push back against that a little bit. I mean just a simple example is if definitions are present having them accompany the codes is a point and then to go on, if definitions are present the ability, let's say, to just make an image of your value sets in your local Apache Server; that's something everybody knows how to do; and a little widget that says, "Put these lines of JAVA script in an HTML page," and when you hover over this, this definition will show up. It's this sort of stuff that is very simple. It's done on Web pages worldwide today and when there makes a huge difference about what exactly did they have in mind when they gave us that code.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Lee Min, I think your card has been up for a while.

Lee Min Lau – 3M
It's been very interesting hearing all of the comments. Let's see if I can express myself somewhat clearly. The thing is that for the 80% of the users out there they are going to assume that if the government puts something out that the definitions, the underlying models, all of this has been done. It's like when I buy a house. I spend no time asking about a foundation. It better be there and better be good. That's all I care.

So for the average user I think the fact that, as Brian said, they have a list that is authorized that will meet the meaningful use ... extending beyond that, let's say if I'm a cardiologist all I care about is that I go to this Web site. I can get a list that sort of can be used as a starter set and that if I have those codes in my system and I send those codes out I should have reasonable confidence that those codes will be accepted and understood and used by other people and vice-versa. If other people send me codes it's going to come from that list. That doesn't mean that the definitions and models and all of that is not there; it's just that from a practical point of view when I'm working I just want that reassurance.

Going back to your ICD-9 examples or ICD-10 examples with exclude and audit, again, that is at the use level. That means I'm expecting that when my coders are coding they will know about the exclude, use for, blah, blah, blah, but when it's all said and done the code I send out that's a valid ICD-9 code. Do you see what I'm trying to say? So there are levels of use and levels of requirement that differ according to the rule of the user. I'm saying that for this one-stop shop you can start at the minimum by saying this is the role. Here's one place where you can at least go get all of your value sets; maybe not all, but this set of value sets and subsets and for each set this is what it's supposed to do. Okay?

Then from that you can extend it. It's like for each of the items a value set here is a definition. If you're interested here is the underlying model. If you're interested, here is more information. When I talk to folks back at 3M you know how I am. They ask me a question. I explain for five minutes and then they say, "All right. Now give me the one-sentence summary," or they say, "Give me the answer in a level that

I care about." So that's what I'm suggesting for this group today, a one-stop shop provides information at these different levels of requirements.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Frank, did you have another comment you wanted to make?

Frank Naeymi-Rad – Intelligent Medical Objects – CEO
Sure. I guess I just ... remove ambiguity as much as possible. Let's make it simple for people to get access to data and to be able to download it, but I'd like to really challenge you a little bit more. I really think you have the opportunity to transform, to really transform what's happening right now. Let's not make this a stimulus, cash for clunker; let's really make something happen right. I mean the bottom-line is if we create subsets and value sets that require additional transformations and translations and mappings within the EHR vendor at the point of care there's going to be confusion over and over.

Codes have to change all of the time. Let's find a foundation that we can actually deliver these value sets and subsets and make them easily embeddable inside this application, make sure it's understandable by informaticists within the organization that they can make the decision at the point of care. Let's not make it a cardiologist value set or endocrinology value set. Let's make it a care delivery services that actually brings real value. That's really what I ask. I think that foundation is going to be so important to make sure that whatever you build becomes something that can be used over and over across time.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Now, just in terms of managing our time here today I am going to suggest that we take a short break in just a few minutes. I know, Brian, you've had your card up, so I want to get one more response on this question. I'm sure we'll come back to this. I know Chris had his card up first. However, Doug has to leave, so I want to give Doug an opportunity to ask his question first.

Brian, after your comment then Doug will ask his question and then I think we'll take a short break while we think about responses, okay? A five-minute break.

Brian Levy – Health Language – Chief Medical Officer
I'll be quick. Just to reiterate something that, Betsy, you said earlier: I think now is a great opportunity for the EHR vendors out there to really begin to differentiate themselves. I think that where we're going to see that is we have two major transitions going on and we're focused on the meaningful use, but honestly, I would argue and I think that providers are very quickly realizing that the transition to ICD-10-CM is really a bigger issue for them and honestly, probably a more costly issue for them. As much as they want to receive our stimulus funds, if they're not going to be getting paid as much as they used to under ICD-10, well, that's a much bigger issue. Certainly, we're spending a lot of time at HLI helping the vendor partners sort of simultaneously and synergistically transition to both ICD-10 and terminologies like SNOMED CT and I think those EHR vendors that are able to do that, that are able to provide the additional context and the additional functionality around the simple lists and stuff that we're able to download, that's really where we're going to start to see the innovation.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. I'm sure we'll come back to this question of sort of what's the minimum starting point. Doug, I wanted to give you an opportunity.

Doug Fridsma - ONC
Thank you. I apologize. I'm going to have to leave here in just a bit, but I wanted to make one clarification about the testimony and that is regarding the C32. My understanding is that the C32, the difference between Version 2.4 and Version 2.5 was actually the ability now to include additional value sets, not just SNOMED. So in fact, ICD-9 should be permissible within the C32 infrastructure.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I can clarify on that. The C32 spec references the C83, which the updated version of that has an explicit example of using ICD-9.

Doug Fridsma - ONC
Yes. So—

David Dobbs – SAIC
The C32 spec, Version 2.5 references the C83 spec, which is a list of data elements that are associated with the segments or the message segments within the C32. It then references the C80 spec, which is all of the vocabulary constraints. So the C80 spec is the one that says procedures shall only be SNOMED. I think part of my point is that we have this HITSP body of work. People are going to be implementing it. They're going to be following the HITSP trails and there is nobody maintaining this at this point, so I think we need to go back and look at some of these things, probably clean them up a little bit, have somebody republish some of these so it is very straightforward.

Betsy Humphreys – National Library of Medicine – Deputy Director
I think when we hear all of the indirect references we already know it's not very straightforward.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes. Exactly. Is there anything else on that subject?

Ken Buetow – National Cancer Institute, National Institute of Health
Yes. No. I had a couple of questions. So they're kind of related and I'm hoping that the panel can help us to address this. So we've had representation from federal partners. We've had representation from the private sector. One of the question I have and I'm going to just ask all three because they're somewhat related is to what degree and how do we drive innovation in this area in a way that kind of reduces our costs, makes things simpler that people begin kind of competing on the things that we value and what would that look like.

Related to that is what is the appropriate role of the federal government that will help enable that kind of innovation to occur. The third part is given that role and the various parts that you have with defining value sets, validating them, defining the standards that you've got, kind of exchange them and the like, who should be the steward of those different parts.

At the end of the day we really have a responsibility with meaningful use until 2022. That's really where the Medicaid program sort of sunsets. How do we create an ecosystem around semantics really, around the value sets that we have there, that creates innovation, that helps us drive down costs, that has the appropriate role for the federal government and that has kind of the different parts of the process with the appropriate stewardship?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think Frank started to put his card up first and then Brian.

Frank Naeymi-Rad – Intelligent Medical Objects – CEO
I think depending on what you really mean by what competition; it is competition around the care delivery and the role of meaningful use as it relates to the care of the patient. I think that's probably the most exciting competition that we need to focus on. I think we need to get more clinical people involved; I mean like people who actually use the EHR. If more EHR vendors come into the marketplace without any physician user, without any actual clinical users those EHRs are not EHRs. They're just the billing systems.

So I think if somehow you can create a structure in which it allows the clinician to be part of the competition, the clinician to be part of the care and the competitions around delivering a better care, reducing the costs for the right reason, I think that's going to be the big challenge. I think there are some activities going, HL-7 for CCD and then activities around the components that actually get generated that can be inferenced on independent of any vendor that allows the clinician activity and getting to this entrepreneur model could be very exciting.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Brian?

Brian Levy – Health Language – Chief Medical Officer
Yes. I mean I think that at the end of the day some of the real innovation that's going to come from the use of this content is not this content, but it's what we do with this content. It's the decision support content that, to me, is sort of the real value add.

As a practicing physician, when I try to explain to my colleagues what I do I say, "Well, I'm trying to standardize some of the languages," they give me kind of a blank stare. They don't understand that ... should they really. But if I can say, "Well, because you're using this sort of standard we can show you a care pathway at the point of care. We can remind you to put your patient on DBT prophylaxis right away. You can better analyze." I mean all of that sort of gray stuff I think is where we're going to see some of the real innovation. Certainly, we'll see some in how the EMR vendors more quickly enable users to enter these codified values, but it's how we're going to be able to integrate this content with valuable decision support content.

Just kind of brainstorming here a bit: Certainly, most of the content exists in the private sector, but there's certainly valuable content, such as the national guidelines that maybe there's some work to taking some of those types of guidelines by the national government and trying to code those whenever possible to the standards so that we can begin to push that process forward more.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think Ken and then Harold.

Ken Buetow – National Cancer Institute, National Institute of Health
Just one, again, experience driven pieces: I think making the rules and the content clear. I think the previous conversation we just had about the C32 is a perfect example of one of the things that blocks innovation. People don't really know exactly what they could or should do. The playing field is pretty clear. The competitive system drives innovation, actually surprisingly powerfully, but when it's really murky about what you're trying to do and how you're trying to do it it actually becomes much more complicated, I think, for people to see where the opportunities are and you spend a lot of time negotiating noise.

I think the role of the federal government actually is to help provide that clarity; not by necessarily dictatorial rule making per se, although that's how it will emerge, but through its power of convening to try to drive not necessarily the consensus, back to Betsy's earlier comment and actually several comments that we're never going to get everyone agreeing on exactly what needs to be done, but hear enough of the majority of the voice to say here's a clear path of what needs to be done. That's their stewardship role; it's to say, "Okay. We brought together the key stakeholders. Here is what is at least the large scale voice and here is the clarity that, at least for now, we're going to present," and go out there and be productive and do cool stuff.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Harold?

Harold Solbrig – Mayo Clinic
Just to focus on what Ken said with just a slightly different perspective: We need to know what our goals are, but we need to be able to measure them. If we can provide measurements they don't have to be easy measurements, but metrics that say we have accomplished or the community has accomplished what we need to accomplish that provides goals for innovators and for people in the world to go out and say, "How do we take what's there and get us to our goals?"

I think the other piece that we need to focus on is it's not just what value are we providing from a government perspective in our ability to measure, but what value do we provide to the healthcare provider. How can the use of these value sets increase the quality of patient care, reduce the cost of

patient care and allow healthcare providers to add additional value and to be fair, to measure the value they provide to communities against other providers? Also, the value we provide to researchers; is there ways to measure what researchers can gain from the shared meanings and elements?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Any other responses on Doug's question about innovation, the ecosystem, government role? Lee Min?

Lee Min Lau – 3M
As Doug said, the questions are related and the answers are related too, so how much innovation or what kind of innovation there would be would depend on what the government's role is going to be in this one-stop shop. If the government is going to say, "All right. We are going to put out a one-stop shop," even though you said not UMLS, but let's say it's NLM that's going to run that and we put out the value sets and subsets that would be the authorized ones and ... then innovation would be in how we use those, how we download, how we distribute, how our customers implement mapping and all of that.

If the government then says, "Okay. No, we're not going to quite do it that way," what we're going to do is to publish maybe guidelines on a more high level sort of idea like we want you to use SNOMED CT and as long as it's on the problem list you have considerable flexibility in how you produce a value set or subset then the innovation is going to be at a different level because then we're now going to be competing on local producers, the more practical use or what have you.

So a lot of this I don't know that we can answer it right now until we know where we're going. So for what it's worth, it still circles back to what the one-stop shop is going to look like. Is it going to look like a Nordstrom's or a Costco?

Doug Fridsma - ONC
Let me just sort of follow up on that. I mean I think you sort of put a better point on it I think and that is we need to think about one of the things that I hope to get from the experts that we have here is what is the role that the federal government can play in sort of driving and getting us to the point where we have value sets and we have vocabularies that are manageable and things. When it comes to one-stop shop you could go to a particular vendor or a particular organization that provides all of that and there could be multiple one-stop shops where they all integrate. You could have a centralized server that everything goes through. You could have top down kind of commanding control of what happens. You could have kind of a facilitated coordination. I mean there are a lot of different models that we have out there and so depending on the path forward and what it is and I'm trying to take some notes about the things that are clear that we need to be able to take a look at, we can have a fundamental change on the ecosystem depending on the model that we approach.

I'd like to think about it very broadly in terms of how we even come up with our value sets, how we reach consensus. Ten years ago we didn't have the kind of technology that we have now that would help to support that. Do the old structures still work if we've got new technologies that would enable new kinds of structures to occur?

So the question really is if we want to get ultimately the use of these to improve patient care are there innovations along the way that will get us there faster, that will get us there better, that will make it more sustainable and what is the kind of model that we should explore to try to have that happen.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Regis, your card has been up for a while.

Regis Charlot – Intelligent Medical Objects – CTO
I think I would truly agree with Ken. I think there is a problem with clarity. We have a chance to work with ... EMR vendors. We're a content vendor, so we provide the terminology that is clear that maps to the standards, the standards being ICD, SNOMED, ICD-10 and so on. The main issue we have and that drives the actual innovation in my mind is what is the standard ... what are we going to do about that? I think the main ... to innovation is we don't know if we can build on that standard. We don't know if we can

go forward with that ... of ideas and people don't know where they are going right now. I'm talking about EMR vendors and I really think about these are the people that are driving .... These are the people that are supplying the software that will be ... toolkits ... our job correctly here.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
David?

David Dobbs – SAIC
I guess I'm somewhat getting at the same theme about clarity, but I might put a slightly different spin on it. I served for several years at the CDC on their Public Health Information Network and we put standards out there for how do you share information between public health stakeholders and from clinical care to public health and from ... to public health. One of the things that we realized was that as you did this and we talked about this, these value sets that you create don't live in a vacuum. They have a specific purpose. So what we did was we pulled together our Interoperability Team, our Messaging Team with our value set team and whenever a value set was developed it had a very specific implementation guide that it was associated with, data fields in the implementation guide and there was that context that flowed back and forth between the specifications. So you knew at a very high level of certainty how those things fit together and what the requirements were.

I think we need to have that level of clarity as we develop this one-stop shop to say here's the value set. Here's the meaningful use standards that we have for sharing information and here is specifically how that value set fits into that meaningful use standard. You could even have the meaningful use standards at the same one-stop shop and then a cross link. You have all of the data elements. You have a cross link to the value sets that are part of them. But clarity is going to really release the innovation because if there's not clarity people spend a lot of time trying to figure out what they need to do to meet the requirements.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Frank?

Frank Naeymi-Rad – Intelligent Medical Objects – CEO
Just building on both Regis and David's comments, the challenge comes when it goes into the actual care delivery and the point of care. The maintenance is another major factor. If you cannot, when you actually invest in this ... it was probably the biggest contribution that you had made and that should be really supported. When you have some foundation people can rely on that that innovation then actually can be built upon, some place that you can say, "Yes. This is it. This is the target. If I build it on this target, if my rules trigger these concepts and if these concepts are maintained correctly, if I can trust the source that's maintaining it," then I think we have moved to a new dimension. We get it and we bring the stuff into the point of care.

If you're going to have innovation it has to be at the point of care. You can empower the physicians and care delivery team that actually can deliver using these applications. Regis is absolutely correct. It is amazing, amazing what a mess we have in some of these applications, especially because of all of the legacy. They have legacy after legacy. The challenges that they have, you need to give them a little bit more direction so they can at least have a chance to remove some of these legacy attributes that they have to maintain because they don't know if they have to remove it or not. That would be my comments.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Harold? Then I think this will be our closing comment on this.

Harold Solbrig – Mayo Clinic
Actually, I'd like to focus on the second part of Doug's other question, are there new paradigms and directions that we can go forward with to do this more effectively. One of the observations I've had over the years of working with the service, the Terminology Services is the SNOMED CTs and the ICDs and the code sets, as distributed, are never adequate for an individual institution. Every institution has to customize, tweak, twiddle, add little things that were forgotten or features that are specific to them. It's

resulted in interesting cases of lock in and interesting cases of incompatibility. In some cases people finally discover that clinic A has developed this wonderful extension that's actually useful. Can we do that? But that's a very slow process.

We have the tooling today that allows requests and changes and enhancements to be made publicly available to be voted on, on a community basis, to be vetted by experts. We have a mechanism, I think, that just using some of the crowd sourcing and other techniques we've got available now allows us to respond much more rapidly to the difference between our understanding of what we think the community needs and what the community actually needs. I think that's a scenario that we should investigate.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Patty, did you have a follow-up on this one or is it a different question?

Patricia Greim – VA – Health System Specialist: Terminology
I was just reflecting on the answers to Doug's questions and just feeling very appreciative for the collective knowledge that is expressed here. I had a few comments about it, but nothing to hold up.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
What I'd like to do then is I'll call a five-minute break at this point and then we'll come back. Chris, I promise you're up as soon as we get back.

(Break)

Judy Sparrow – Office of the National Coordinator – Executive Director
I'll turn it over to Jamie Ferguson.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
We're going to turn next to the first card that was turned up to ask a question of this panel, Dr. Chute.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Let me add my compliments to all of you for what I think is a very thoughtful and insightful contribution to our deliberations. The conversation has moved on a tad since I first raised my card, so let me rephrase a question or reframe it.

We've heard substantial variability on two things and in a rare attempt to be concrete I'm going to focus on two specific questions. One: What do you think the product is? Because we've heard the spectrum from fairly dumb downloadable pairs of codes and values to sophisticated services and everything in between that might form a presumptive architecture for EHR vendors in a transformative way. That's a huge spectrum. So what are we talking about? What's the product?

If we're going to go back to the Nordstrom/Costco variation, who is the customer? Is it the rural physician in southern Minnesota in a solo practice? I don't think so. Or is it EMR vendors or is it the public or is it somebody in between? It's very hard to define what a product is until you have some understanding of who is going to be buying it, so with those two provocative, but relatively concrete notions, let you answer.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Lee Min first.

Lee Min Lau – 3M
This is Lee Min from 3M. I think the point is that if you ask us, being the greedy people that we are, we'll tell you that the product should span the whole spectrum. You can provide the user; we'll define who the user is in a minute; that whole variable, the whole range, depending on what they come in for. So again, you're asking me for a wish list now. That one Web site would allow me to go in and ... all I want is a dumb-dumb list, just download this one thing today versus I want an entire discussion, background, everything ... model that my application can link directly to and so on and so forth, so what the product is

really depends on what business and what use you want to make of it. But in terms of capability I can certainly envision spanning the entire spectrum.

So if you then go down to the practical and say what is practical for the government or for this group to do, then it's back to who you decide you want to support in terms of the user. If you're up front and say, "Look, guys, this is not for the generic lay person to come in and just browse and learn terminology. I'm targeting this at implementers, which means that I expect you to have someone to help you do stuff," then you can target this product, reduce the range of the product down to a certain level. Do you see what I'm trying to get at? A simple example is like I am actually very low tech, so for instance, taking a laptop I would get to the level of saying don't explain to me all of the five, six, seven different models I can have. This is how I do my work. Just give me the laptop and be done with it.

Again, it's not that I'm trying to give you fuzzy answers to very good questions. It's that it really depends on what this group decides best suits the country's interests.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Brian, I believe yours was next.

Brian Levy – Health Language – Chief Medical Officer
I think just to try to brainstorm and directly answer the question, I think that the initial users of this are going to be the EMR vendors, the terminology service vendors, like us, who sort of aggregate all of this content. As I mentioned earlier, I think that we will see not the rural physician in a small town at a small office, but we will see CMIOs at large hospital systems, who, as I said earlier, want to be able to go in and ensure that their vendors are using the right sets of content.

To that point, I think that initially having the ability to simply download all of this content with the appropriate versionings and dependencies and metadata set, I think those are the initial uses of this. As I said earlier, I think that I could see that having a terminology service underlying this might be useful for the more advanced kinds of users. I don't see that as an initial requirement.

One of the issues too is that, as I said earlier, this is not going to be the only place we have to go and get actual content, so it won't be the one-stop shop. It will be the one-stop shop for meaningful use related kinds of content, but it's not going to be for the 100 other terminology sets that are required for the payers or for international sites. So if we make it too complex and if we develop a really robust terminology service, but yet I still have to go to a million other places to get my content then that terminology service may not be that useful for me.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Let me turn to Regis next.

Regis Charlot – Intelligent Medical Objects – CTO
One thing I would like to add to Brian is ... outstanding also in ... from the time we have terminology it takes a long time to get the processes, to get vendors to adopt those terminologies and there is really an issue of a complexity for vendors. There might be 15 or 20 vendors on the market. It takes, for most of these people, six months to a couple of years to get the software, to actually get that content to come in front of users.

So the thing I would like to stress is a decision where ... drawn as a standard has really affected the market. People don't know where they are today and they withdraw specific features from their software.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
David, did you have a different point?

David Dobbs – SAIC
I did and I put my card down, but I'll briefly speak. Dr. Chute, I think that's a very key question you ask. What is the product and who are the users? Who is the customer for that? I'd switch it around a little bit

and say first you have to talk about who the customer is and agree to that. Once you have the vision and the common understanding of that customer then you can say what does that product need to be to be able to serve that customer and their needs.

I'm going to, I guess, repeat a little bit of what Brian said. I think the customer is the healthcare implementer, so it's the EHR implementer. It's the hospital CMIO. It's the people who are trying to put this terminology into their EHR applications and their other clinical applications.

I think it's also important to say who is not the customer of this and to agree whose needs won't be met initially through this. I think as the Committee goes through this and starts thinking about who the customer is and then specifically say in this phase these people aren't the customers, and I'll give some examples of people who may not be the customers in phase one of this one-stop shop. You know the phase one customer in the context of giving them tools to do their work may not be the value set developers. They might be off developing their value sets in the same way that their currently developing their value sets and then provide that content into this one-stop shop. But I think those types of discussions need to be had so that everybody has that clear understanding of the customer and then once that's arrived at the requirements for that customer could be much more easily defined.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Ken?

Ken Buetow – National Cancer Institute, National Institute of Health
Very insightful parsing, as always. With that said, I actually would add, I think an additional dimension that's going to be necessary for clarity to answer the question because I think the customer is confounded in this instance because of the very nature of the fact that this is the meaningful use, so at the end of the day the product has to support meaningful use and I will lean heavily on the word use as Harold has been leaning on it as well.

The additional piece I would add is distribution channel. You can't consider the difference between wholesale and retail unless you have a distribution channel. I would argue personally that this is a wholesale place, so the bottom-line is the purpose of this one-stop shop is as a wholesaler. Maybe we're going to go more to a Costco model, but even presumably further away from Costco because in this instance it's the people who provide to Costco. It's the people who provide to Wal-Mart. It's the people who, theoretically, provide to Nordstrom's as well. So it's that whole large, back-end piece of what's necessary.

Now, that being said, you still have to have product that meets the customer, so both Nordstrom's, Costco and whatever still have people coming into the shop to buy stuff and you have to support what those are. So I think that the product has to support the meaningful use, but I think the true purchaser or the interaction of this is a distribution channel and that this is a wholesaler and that the wholesaler here is EMR vendors. It's large-scale folks that have the ability to do something. I couldn't agree with you more. I can't see a small doc in Arkansas or in North Dakota spending a lot of time on this site, trying to figure out what to be doing. I'm trying to choose two poles. In the middle America here I think its primary need has to support the wholesale consumers, the people who can convert this into other things, but it has to have the richness of the product to meet those end customer needs.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Frank, something you wanted to add?

Frank Naeymi-Rad – Intelligent Medical Objects – CEO
Chris, obviously, you are one of the leaders in this whole space and questions like this from you have multiple meanings behind it, so I have to be very careful how I answer this, but I really think in different analogies it's a seed. You're planting a seed for a tree to bring the fruit. So that's what you're trying to do if I am understanding with this meaningful use movement. So the question here is at this stage of planting what that seed is and what fruit it's going to bear. You need to articulate it. This Committee needs to articulate what their expectation is to those people, who are going to basically pick up these

seeds and take it and try to plant it. I would say that's basically what's not clear right now. It's not really clear what's the value set, what's the subset and it's been going back and forth in my organizations. How do you define it? Is this really a theory or is this a factual event?

By that saying I think in the background I firmly believe the direction that the Committee is taking and some of the people who are involved have a real clear understanding where they want to take it and how they want to use it, especially you. So think what we probably would need in the marketplace is to have some vision casting. You know, here is the value set. This is what I expect ....

Now going back to the second question: Who is the customer? I think customers are people who really genuinely believe in and comply with the meaningful use. There is a catch at the end of the hook and if people want to get to it I think that is really a not right way sometimes to handle something, but maybe the only way. So I would say our job is, as a vocabulary vendor, to make sure that that is not just a one-time event; to make sure that whatever we do for our vendor partner that that is a lasting event and be able to comply to the goal and objective that you have; to make sure that this seed is planted in the right dirt and is seeded by updates and watered or cared for by watering it and getting it to the right place that you want to stake it. So we take directions from you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Harold?

Harold Solbrig – Mayo Clinic
To follow on a little bit with what Ken said, maybe the customer metaphor and the Costco whatever falls apart. I mean I said who is the customer; I think our customer, the community that benefits from what we do isn't going to be an EMR vendor and chances are it isn't going to be a rural physician either. It's our end customers or the healthcare consumers, healthcare researchers and people that pay for healthcare. I mean that's, if I understand it correctly, our primary motivation for doing this.

EMR vendors, by whatever rules, etc. made are forced to make changes in their practice that may be non-optimal for them. For instance, shared use. There is a lot of incentive for an EMR vendor to not have shared use, to be honest. So the notion of an EMR vendor as a willing customer is where the metaphor sort of falls apart. The EMR vendor, to continue to practice, needs to be able to do what we ask them to do for our end customers.

The other thing that I have to say; I couldn't disagree more with Ken is the rural physician. The notion of setting something up where we have a two-tier system and where I either get health care from somebody that generates non-sharable and non-distributable data or I go to big organizations that play in the big game I think is completely wrong. I don't think there's any reason that we can't make what we put here accessible equally to the rural physician with a boutique medical management practice and to a big community, like Kaiser and Mayo. I think leaving the rural physician out would be a huge mistake.

Ken Buetow – National Cancer Institute, National Institute of Health
I need to clarify that that was not my point. My point was I don't see the rural physician spending a lot of time at the National Library of Medicine browsing large-scale infrastructures and consuming of CTS2 and leveraging the services and doing that sort of work. So I was actually arguing that they are the true end consumers of this, but they are not shopping at the one-stop shop.

M
It gets at the whole question of whether it's a direct or an indirect consumer.

Ken Buetow – National Cancer Institute, National Institute of Health
But the capabilities and the content need to be supporting the entire spectrum, so that's why I was actually over leveraging our Nordstrom and Costco metaphor. They need to support both sets of users. The true consumers of the information are the entire biomedical spectrum, but I'm not sure that my personal bias would be that the one-stop shop, in terms of its delivery of stuff probably is going to work

through intermediaries is what I guess I was trying to use, to extend the metaphor by saying distribution channels. So I think there are going to be distribution channels that result in that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think we've heard a variety of opinions, some expressing a preference for direct services to be provided by the one-stop shop for the actual end user of the EMR and others saying that really the indirect model. Perhaps we need a mechanism that could potentially serve both. I'm not sure. So, Harold, are you—?

Betsy Humphreys – National Library of Medicine – Deputy Director
The other thing, of course, is that the end users are going to be a wide spectrum. This reminds me somewhat of the conversations that we had many years ago when certain people or certain groups were maintaining that it was never relevant for a patient to read an article from *JAMA* or the *New England Journal of Medicine* and obviously, there have been great information services. We've done some of them working off NCI and other content for the consumer, but that doesn't mean that some of those people don't read the articles and shouldn't if they want.

So I think the issue is really to say who are we serving. You describe what you have there. I'm actually thinking that even for the wholesaler, something allowed him to look at the thing so he could understand whether this particular value set had problems in it or procedures would probably be useful even for those users.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think we'll turn to Brian next.

Brian Levy – Health Language – Chief Medical Officer
One of the challenges too that we face is that this content is to some extent useless unless it's in the EMR or unless it's in my practice management system and so I could be the rule doc and I could download the list of problems, but then what do I do with it?

We're actually finding that it's not so easy to get content into the EMR. EMRs tend to be kind of closed shops and so we need to work together with the EMR vendors and other HIT vendors to more readily enable their applications to consume local kinds of content. Until that happens in a wider spectrum we have to rely on the main distribution channel being the EHR vendor or the other HIT application vendors.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Regis?

Regis Charlot – Intelligent Medical Objects – CTO
Yes. There is another thing that I would like to counter Harold on what he said. The actual EHR vendors have a clear incentive to work with others, so HITSP 32 is ... now, are we going to challenge that now ... CCDs and CDAs ... this is happening today and the reason why we want to work together is in most cases, in large institutions there are many being just in time and people force them to actually get the data to go through, so not only do we need technology so it's being done and the knowledge to actually get through ... is what we need today.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Russ?

Russ Hamm – Apelon
Russ Hamm with Apelon. I think there are both direct and indirect customers that are going to end up being the users. By providing structured content in a consistent format that conforms to a set of minimum requirements for terminology model and making that content available using a set of consistent services it provides a level playing field, a basis for innovation for the vendor communities to then use that content to drive end products that can actually be used by a physician practice in southwest Minnesota or southeast Minnesota.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
David?

David Dobbs – SAIC
Just, I think, an important point when we're looking at who is the consumer here. When I look at EHR meaningful use I see a number of different moving parts that all have to work together. There is the CMS final rule. There is the HHS/ONC final rule around the standards. Then there is the certification body that's going to go out and certify that these EHR systems actually do what they're supposed to do. So I would consider the certification body as one of the customers for this because you would expect what's being distributed through this one-stop shop for vocabulary that works with the interoperability specifications from ONC is going to be certified by the CCHIT, so I would highly encourage considering those perspectives in those linkages.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Suresh?

Suresh Srinivasan – National Library of Medicine
I think just an observation that raised in my mind from Chris' comment is we're in the position of asking if we build it will they come in the sense that who are we incentivizing, are we incentivizing the right parties? Because we have the EMR vendors in the middle, who are indirect consumers, if you will; and the end users, who are the real incentivized folks are the rural physicians or the physician community and if the EMR folks don't come to the party all of the incentives are not going to make a difference at the rural physician level. So I think it's just something we have to think about; if we're targeting the right folks.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
One more on this one, Frank?

Frank Naeymi-Rad – Intelligent Medical Objects – CEO
Just one item I forgot. What about the payers? I mean have we thought about the role that they're going to play in this interaction? I guess that's a question back to you, Chris.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
I think payers are obviously deeply impacted by interoperability and ostensibly, the improved care that would come from information exchange. It really gets at the whole question of payment reform, which is are we improving the healthcare environment. Are we improving the healthcare system? If so, overall costs to society and hence, payer costs are ostensibly lower. So yes, but what hurts the brain here are the levels of indirection and the whole machine recascade that needs to be set in place to enable that shared common end game of improved healthcare for all. I mean that's what presumably health reform is all about.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Next I want to turn to Patty Greim for our next question.

Patricia Greim – VA – Health System Specialist: Terminology
I just want to say that I heard clearly from you, Harold, at least that it's important to identify how we're going to measure our progress as we're seeking increased patient safety, increased quality of care and positive consequences of meaningful use. I'm reminded that the Joint Commission is retooling their quality measures to be automated. The National Quality Forum is retooling quality measures, right?

M
(Inaudible.)

Patricia Greim – VA – Health System Specialist: Terminology
Assisting. There are all of these quality measures that are going to require value sets that we haven't even seen yet if I'm reading the future correctly. We haven't had to accommodate value sets for these purposes yet and they will be measurement purposes. If I'm reading the future, the credentialing bodies

are going to use these for how to evaluate EHRs. I'm hearing from our public comment yesterday that some of the value sets that are being created right now aren't even harmonious. I mean the targeted values that are identified in SNOMED for one quality measure are using different code sets or different code for something than another one is.

So I guess I'm shifting my listening from one of keep it simple to keep it clear. I think the role of government is really to be clear. That's the message I'm hearing today, because we don't need to keep it simple because we have incredible talent here. There is incredible retail talent for our one-stop shopping, so if the government can wholesale clarity I think we'll have done a good job.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Before we get into responses, Floyd, did you have a—?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Yes, if I could. Actually, my comment was, I think, along the lines of Patty's and related to a comment David Dobbs had made about who is not the customer. I think I heard very clearly; and admittedly I was on that panel; so I said very clearly I thought yesterday that the creators of value sets, the quality community as one, by having this distributed into a many flowers bloom mentality creates different value sets for the same concept that are not necessarily the same, as Patty said. I heard clearly from the clinical decision support community in creating value sets or ... recommendations in an EHRQ project that they had some difficulty doing that and ended up reusing ones from the quality work, so if there is inconsistent input then if the customers are only those receiving output how would that provide the right information to start with.

Betsy Humphreys – National Library of Medicine – Deputy Director
Let me make just a comment on that: In my mental model of this I am a firm believer that we need clarity about who is doing what and an infrastructure and tools that allow people, who are creating value sets and vocabulary in various spaces to work in a reasonable way and take advantage of each other and so forth. I am also a believer that we need greater clarity on the distribution for people who are wholesaling whatever. I am not necessarily certain that we want to have a one-stop shop that does both of those things.

I mean we may have an area that is focusing on get the stuff out and we may have another group of parties who are already responsible for creating content in a variety of areas who have to be knitted together in a better way so that we do not create conflicting value sets of the same thing for one thing, but also that we make it very simple for people who have to create value sets from standard terminologies, that we all know which version they're in and they can't make a mistake and use an old one and they're working in an environment where it's impossible for them to somehow mistype an identifier or something and end up with something that doesn't have validation. So I think we need both of those things and I'm not necessarily certain that our fastest way forward is try to put them into one grand scheme at a time.

That doesn't mean that people who are providing boutique services in these areas might not participate in both infrastructures or feed into both, but that we wouldn't necessarily say if we're trying to put a one-stop portal or something over all of it we were trying to do all of those things at once. That's how I've been thinking of it and I know that there are multiple different ways to think of the same thing.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So as expanded by Floyd's and Betsy's comments, back to, I think, Patty's question do we really need simplicity or do we just need clarity and then use the variety of services and service providers that exist in the community? David?

David Dobbs – SAIC
One of the things that Patty said that really peaked my interest and it might not get at your main point, but I think it's an important point is that you said that there's the possibility that some of these value sets for the measures are incompatible with each other. This measure uses this certain set of codes for diabetes and this other measure uses a different set of codes for diabetes. That's going to happen because you're

going to have different people developing measures and mistakes are going to be made and different viewpoints are going to be there.

So I think what this one-stop shop means is that vocabulary content and the way we've talked about this at SAIC is that you've got sources, vocabulary sources. So as your sources or suppliers of vocabulary content, the measure developer, the value set developers and het measures, the value set developers of the implementation guides, as they provide that content in there needs to be a quality assurance step that goes across to make sure that that data, as it comes in, works together well with the other vocabulary that's already there. That's very important so it does provide that clarity that you have to the end implementers that I'm going to get this value set and it's going to work with all of the other value sets that I have and I'm not going to spend a day and a half running around trying to figure out why it doesn't work with this one. I think that's an important step I guess.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Just to rephrase your answer, if I'm hearing you correctly, you're saying that the one-stop shop can't be just merely a publication or a distribution channel. It really has to include quality assurance processes?

David Dobbs – SAIC
Yes.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Brian, I believe you were next.

Brian Levy – Health Language – Chief Medical Officer
Actually, I was going to argue much the same point only raise the question that I think there does need to be validation here, whether or not the one-stop shop does that validation or not I'm not sure. It's something I haven't really thought of.

Betsy Humphreys – National Library of Medicine – Deputy Director
It's interesting. I think this is an ... terminology if you're publishing this stuff in some way, shape or form from a place it's kind of the last place where you make sure that in the transmission to you half of the file didn't get dropped or something. So I really feel that if you're an official distribution site or feeding one then the last place where somebody might actually pick up the file has to do not the content analysis, but just something that somebody didn't click the wrong button and output last year's file format instead of this year's or something or it didn't get dropped on the way to the store.

Brian Levy – Health Language – Chief Medical Officer
I would agree. I mean I think the issue of content validation, as you put it, is fairly hard. What is the subset of diabetes SNOMED codes? I think we could spend the next several days debating that and not come to the right answer. But with that said, I think that does raise the point of something we need to think about more. Who should do that content kind of validation or should we do some of that or should we let it be kind of a market driven process where the EHR vendors and the folks like us say, "Well, here are some issues," and what not?

Betsy Humphreys – National Library of Medicine – Deputy Director
Well, if it's part of a quality measure that everyone has to apply then, obviously, it has to be done in what we heard about yesterday in a good process that brings in the experts and whatever, but eventually comes out with a value set that everyone has to apply; otherwise we're measuring different things.

Stuart Nelson – NLM – Head, Medical Subject Headings Section
Just a comment about it: It's hard enough to get vocabulary suppliers to be consistent with their own stated format.

M
Yes. Absolutely.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Harold, I think you were next.

Harold Solbrig – Mayo Clinic
The combination of the comments on measuring and the questions of how big does it have to be made me think of some techniques that are used in both, automobile manufacturing and software developing these days under the rubrics of LEAN or AGILE, but the key premise on both of those strategies is that we recognize up front that our perception of the problem space is flawed and there is no way we are going to get it right to start with. So what we need to do is settle for the minimum amount that we can try to get right the first go-round; establish a measure that says how have we succeeded; do an incremental change; take the measures; use that to adjust our goals and to continue forward.

I think in particular when it comes to, for instance, terminologies not lining up, whether the content is adequate, whether we're meeting the goals of the credentialing and quality communities and what have you, the only way we're going to get there is by doing something and then most importantly, providing open feedback channels. That's another aspect of the AGILE or the LEAN development system is you measure, but you also allow your customers to say, "No, this didn't work," very quickly to get it up to the top so that you can do the next cycle.

I think this would be an ideal opportunity to try to do that, because what I don't want to see happen is spending three years gnawing our fingernails with did we get it right, do we have it enough, because I can guarantee we won't. But let's try to develop that feedback cycle.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Frank?

Frank Naeymi-Rad – Intelligent Medical Objects – CEO
I 100% agree with Harold. I think this is all about really clarity of the intent. Make sure that's clear enough so people can challenge it. If they cannot challenge it you don't have the feedback. You're not going to be able to get that innovation boiling and more and more of our clients are actively getting into data warehousing, able to look at the data better, so these value sets and subsets can become a very effective tool for them to challenge it. I think I would say I 100% agree with Harold.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Lee Min?

Lee Min Lau – 3M
Well, I think there's a difference between planning or recognizing everything versus doing everything, so I would say, for instance, the one-stop shop you would really lay out the entire high-level plan or view or whatever you want to call it, the big picture view and recognize all of the steps, all of the sub-goals, all of the processes and all of that and then make a decision about what you're going to do now, what you're going to do in a year's time. Lay the expectations ... and all of that.

But it's not ... if you plan it all you must do it all. It's also not a ... thing because I don't want to do it all I don't want to plan it all. Do you see what I'm trying to say? Because it's like take Costco. I'm sure Costco has surveyed and decided about all of the things it could possibly sell and then you know how Costco zooms into selling only a few things in each category and not all of the categories either. So I think there is a possibility to do this in a wise manner and still meet the needs of most people. Again, meeting their needs doesn't mean you don't hear complaints. It's just totally two different topics.

So I think there are ways to meet, to accommodate and get the greatest good out of this, but what you need really is beyond technical requirements or functional requirements you need the process or the use cases and beyond goals you need the sub-goals or the actually ... steps.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Now I think we're actually out of time for this panel, believe it or not. Although I'd love to go on for additional hours I think we are at our time for this panel. I just want to thank everyone very, very much. I really appreciate your participation here today. Let's have a round of applause for the panel. Thank you. Thank you very much.

We're going to have a brief Task Force discussion here. Chris, do you want to start?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
I think thinking back over the past two days and indeed what the panel here has brought forward, there's a meta-consideration, if I might phrase it that way, that hasn't been clearly articulated, but let me make an effort to do so. I think there is an implicit expectation that whatever the government does that it becomes predictable. By that I really mean we all know that NCHS will, twice a year, create versions of the ICD-9 and we can depend upon that.

We know when it's going to happen. It's like clockwork in a sense. They did change the schedule a few years ago. They went to twice a year, but other than that we got over it. For the most part it is a predictable phenomenon and I think by analogy whatever emerges in the context of terminology services and provisioning of value sets that must equivalently be a predictable, understood phenomenon for whoever the consumers might be broadly stated.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Floyd?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
To follow on to that, I think what I did hear between yesterday and today is yesterday we heard more about some of the inputs to create value sets and in the afternoon, users of and here a lot of attention to users of and needs. I like Betsy's comment. Perhaps we have to develop the Costco and the ... wholesale and then figure out how we merge them later. But it's very clear that the clinical decision support community has had this problem of what they've called the curly braces. They want to say something. They put it out in their rule and it's up to you to decide what that means, but they want to determine more clearly what that means. It's the same issue of quality measures developers have had.

The funding to those communities created has not been a stimulus package and they don't necessarily have that capability for each to gain it and add it. It's expensive to create an economy of scale and have the government provide some resource that they could equally use and share among themselves, which is what I heard in the panel in the beginning yesterday. It would be very helpful so that they could be implemented in a standard way at the other end. Validation is certainly required.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Betsy?

Betsy Humphreys – National Library of Medicine – Deputy Director
I agree with everything that's been said and I just wanted to say that I really resonated with Patty's comment about maybe we need clarity more than we need simplicity because it brought to my mind the following. I think truism, which is clarity has to precede simplicity. You can only simplify what you understand.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right. I just have to say I was making some notes here on how I was going to summarize some of the themes of the day and before Patty actually asked her question what I wrote was that the government must provide clarity and stability and predictability, both what is required, what standards, of whom and by whom and for what intended purpose. That was my number one overriding theme for trying to summarize the data. Stuart?

Stuart Nelson – NLM – Head, Medical Subject Headings Section

What I have been listening to is a lot of discussion about value sets and subsets and I think I understand what a value set and subset is even less than before. One thing that I think that we need some clarity on is our definitions and there has been a fair amount of discussion about the metadata that needs to be associated with value sets. We really need to have some real clarity about how we describe a value set and how people understand its intended uses and so forth. I think that that's right now kind of a vague, general recognition that we need to do it, but we don't really know how to do it yet. I think it's something we need to consider.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Other comments from the Task Force members summarizing? Okay. Amazingly, we're actually on time. Again, I want to thank our panelists for their participation today and I'll excuse the panel. Thank you very much.

Judy, I think we're just about ready for the public comments.

Judy Sparrow – Office of the National Coordinator – Executive Director
Yes we are. It's that time. If there's anybody in the room, who wishes to make a comment, please come up to the microphone. We have Bonnie here in the room.

Bonnie Wester – University of Minnesota
Bonnie Wester, University of Minnesota. One of the questions that Chris asked was who the customer is. One of the responses that I didn't hear clearly, but does reflect some themes that I have heard over the last two days is that training on the use of vocabularies is critical. David repeated that today. It was in our testimony yesterday. The ONC has invested millions of dollars. The University of Minnesota has gotten $5.1 million of that dollar to educate workforce to be prepared to be enrolled, in order to be implementers, leaders in many other roles. So we need to be really clear that one of the customers that were not addressed today is, in fact, academic centers. We need to be making sure that we're addressing faculty and students, so I teach nursing informatics and health informatics students and we teach a course called Knowledge Representation Interoperability.

Listening for the last two days has been extremely insightful as a faculty member about what it is that we need to be teaching our students to make sure that they're prepared to be the leaders and the implementers for the future. So I just want to reiterate the importance of academia being involved as a key customer.

My second point that I want to say is that there are assumptions that I've been listening for, but not clarity on those assumptions in regards to if we have a one-stop shop that somebody has to do something that doesn't exist today and that, of course, there has to be some funding that goes with that, but nobody has clearly said who and nobody has said that there's money. In our testimony yesterday one of our recommendations was that the National Library of Medicine has a foundation with many tools that are already available and if we want to be up and running fast it would be a neutral place to consider as a possibility. I'm not saying it's politically the best place, but it seems logical in my mind that that might be, but I think making a recommendation of whoever that is, without also recommending that of course there's funding would make no sense. So I want to be really clear on the books that we must ask for funding in addition to support the work. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thomas?

Thomas Bizzaro – First DataBank
I'm Tom Bizzaro with First DataBank. First DataBank has 30 years of experience in providing value sets to the community for use in real-time, point-of-care, systems development. I would caution that the vocabularies that we are now going to use going forward, which will become national standards, which First DataBank endorses and supports, need to be timely. They need to have a way for feedback to come into those vocabulary providers from the users and they need to understand that we are now going

to be using this information at the point of care for the patient and that the importance of the use and the implementation of these vocabularies is going to affect that patient's care. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
We do have one comment on the phone. Would you please identify yourself?

Shelly Spiro – Pharmacy EHIT Collaborative
My name is Shelly Spiro and I am the Director of Pharmacy EHIT Collaborative. It's a collaborative of nine of the national pharmacy associations. The Collaborative is focused on ensuring that technical standards are aligned with the nation's growing need for all-inclusive, clinical services provided by pharmacists in all practice settings. Pharmacy practitioners are providers excluded from the meaningful use of the electronic health record incentive payment, but the services provided by these pharmacists, especially medication therapy management, are in the role to all providers using the electronic health record in a meaningful way. The pharmacy community is in the process of developing a value set and this value set will be using NTM CPT and SNOMED CT based codes. These codes relate to the reasons, actions and outcome measurements used by practitioners providing medication therapy management services to assure the meaningful use of the standard for pharmacy practitioner electronic health records.

My question to the Task Force is as the medication therapy management value set is developed, what does the pharmacist community or, for that matter, other providers not mentioned during this meeting, need to do to keep the Vocabulary Task Force informed about these other types of value sets being developed.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
My response on that is that our focus really, our initial focus, really is on the things that are specified in meaningful use and that this particular forum is probably not the right place for that input, but we'd be happy to help to receive it and help forward it on to ONC for consideration.

Judy Sparrow – Office of the National Coordinator – Executive Director
We do have one final comment on the telephone.

Sinbad – CDC Contractor
Hello. My name is Sinbad .... I'm a CDC Contractor. I have a question about the versioning and I think yesterday Betsy also mentioned about scheduled releases of the code system. Really, it looks like there are three sets of versioning or releases going on. One is the code system releases, like LOINC and SNOMED. They have their own schedule releases.

Then based on those releases value sets would be updated. That's another update actually, a scheduled release that may happen from different distribution sources.

Also, in addition to these things, implementation guides may not use the updated value sets. Some implementation guides may use the latest value sets. Some implementation guides may be using a previous value set. I think I would appreciate if the Vocabulary Task Force would really consider the actual implementation of what value set is associated with an implementation guide. That's what really the Windows and other people are looking into. It's not just the value set alone.

Judy Sparrow – Office of the National Coordinator – Executive Director
All I can say is that's a very good point. Thank you to all of the commenter's. Jamie?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. I think the meeting is adjourned then. Thank you very much.